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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,595	06/07/2002	Albrecht E. Sippel	WEICKM 14	5887

23599 7590 10/05/2004

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EXAMINER	
GAMETT, DANIEL C	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,595	SIPPEL ET AL.	
	Examiner	Art Unit	
	Daniel C Gamett	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-35,36-43, 61-63, 67-70, 72, and 73, drawn to fusion proteins, DNA encoding said fusion proteins, expression vectors comprising said DNA, cells comprising said expression vectors, and assays for "suitability of a test substance as ligand", screening for unknown ligands, or identifying a ligand that binds to a nuclear receptor.

Group II, claim(s) 44-48, drawn to an assay for detecting the presence of a nuclear receptor ligand in a sample.

Group III, claim(s) 49-51, drawn to an assay for quantitative determination of the concentration of a nuclear receptor ligand in a sample.

Group IV, claim(s) 52-55, drawn to an assay to determine whether a compound can alter the binding affinity of a nuclear receptor and a known ligand.

Group V, claim(s) 56-60 drawn to an assay for whether a polypeptide has a ligand binding function of a nuclear receptor.

Group VI, claims 71 and 74, drawn to a method for identifying polypeptides which have ligand binding function of a receptor.

Group VII, claim 73, drawn to a pharmaceutical comprising a ligand.

Group VIII, claim 73, drawn to a pharmaceutical comprising a compound.

Group IX, claim 75, drawn to use of certain ligands, compounds, polypeptides or proteins for developing derivatives therefrom.

Group X, claim 76, drawn to a method for preparing ligands, compounds, polypeptides by derivatization of ligands, compounds, and polypeptides.

Group XI, claim 77, drawn to a DNA molecule that encodes a polypeptide.

Group XII, claim 78, drawn to the use of a DNA molecule for preparing a pharmaceutical agent.

Group XIII, claims 64-66, drawn to a kit wherein the fusion protein present therein comprises a second domain comprising a polypeptide or protein suspected of having a ligand-binding function of a nuclear receptor.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature of a method for determining the suitability of a test substance as a ligand for a receptor section of a nuclear receptor, which is not required by the other products of Groups VII,VIII, XI, and XIII and methods of Groups II-VI, IX, X, and XII.

Group II recites the special technical feature of detecting the presence of a nuclear receptor ligand in a sample which is not required by the other methods of Groups I, III-VI, IX, X, and XII.

Group III recites the special technical feature of quantitative determination of the concentration of a nuclear receptor ligand in a sample which is not required by the other methods of Groups I, II, I, IV-VI, IX, X, and XII.

Group IV recites the special technical feature of determining whether a compound can alter the binding activity of a receptor section of a nuclear receptor in relation to a ligand, which is not required by the other methods of Groups I-III, I, V, VI, IX, X, and XII.

Group V recites the special technical feature of whether a polypeptide has a ligand binding function of a nuclear receptor which is not required by the other methods of Groups I-IV, VI, IX, X, and XII.

Group VI recites the special technical feature of a method for identifying polypeptides which have ligand binding function of a receptor which is not required by the other methods of Groups I-V, I, IX, X, and XII.

Group VII recites the special technical feature of a ligand which is not required by the other products of Groups I, VIII, XI, and XIII.

Group VIII recites the special technical feature of a compound which is not required by the other products of Groups I, VII, XI, and XIII.

Group IX recites the special technical feature of use of certain ligands, compounds, polypeptides or proteins for developing derivatives therefrom which is not required by the other methods of Groups I-VI, X, and XII.

Group X recites the special technical feature of a method for preparing ligands, compounds, polypeptides which is not required by the other methods of Groups I-IX and XII.

Group XI recites the special technical feature of a DNA molecule which is not required by the other products of Groups I, VII, VIII, and XIII.

Group XII recites the special technical feature of using a DNA molecule for preparing a pharmaceutical agent which is not required by the other methods of Groups I-VI, IX, and X.

Group XIII recites the special technical feature of a kit which is not required by the other products Groups I, VII, VIII, and XI.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of the second domain of the fusion protein of claim 1 (" a ligand-binding function of a nuclear receptor") are as follows:

a. Steroid receptor

b. Vitamin D receptor

c. Thyroxine receptor

d. Dioxin receptor

e. Retinoic acid receptor

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claim 7.

The following claim(s) are generic: Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (*a*) is a steroid receptor. This special technical feature is not shared by any of the other species.

The special technical feature of (*b*) is a vitamin receptor. This special technical feature is not shared by any of the other species.

The special technical feature of (*c*) is a thyroxine receptor. This special technical feature is not shared by any of the other species.

The special technical feature of (*d*) is a dioxin receptor. This special technical feature is not shared by any of the other species.

The special technical feature of (*e*) is a retinoic acid receptor. This special technical feature is not shared by any of the other species.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of activities of the third domain of the fusion protein of claim 1 ("an activity able to activate a signal pathway connected to Ras protein") are as follows:

f. The activity of a constitutively active Ras protein

g. the activity of a functional guanine nucleotide exchange factor

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 10, 11, 29, 30.

The following claim(s) are generic: Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (*f*) is the activity of a constitutively active Ras protein. This special technical feature is not shared by any of the other species.

The special technical feature of (*g*) is the activity of a functional guanine nucleotide exchange factor. This special technical feature is not shared by any of the other species.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of amino acid sequences of the third domain of the fusion protein of claim 1 are as follows:

h. derived from the amino acid sequence of CDC25 protein from *Saccharomyces cerevisiae.*

i. derived from the amino acid sequence of SOS protein from a mammal.

j. derived from the amino acid sequence of an SOS-like protein from any organism

k. "An amino acid sequence which is derived from the amino acid sequence of a naturally occurring guanine nucleotide exchange factor ...by attachment, substitution, deletion, insertion and/or modification of one or more amino acids or groups of amino acids"

l. "An amino acid sequence which is derived from the amino acid sequence of a naturally occurring Ras protein ...by attachment, substitution, deletion, insertion and/or modification of one or more amino acids"

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 12-14,29,30.

The following claim(s) are generic: Claim 1, 23, for example.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

> The special technical feature of (*h*) is the amino acid sequence of CDC25 protein from *Saccharomyces cerevisiae*.. This special technical feature is not shared by any of the other species.
>
> The special technical feature of (*i*) is the amino acid sequence of SOS protein from a mammal. This special technical feature is not shared by any of the other species.
>
> The special technical feature of (*j*) is the amino acid sequence of an SOS-like protein from any organism. This special technical feature is not shared by any of the other species.
>
> The special technical feature of (*k*) is an amino acid sequence which is derived from the amino acid sequence of a naturally occurring guanine nucleotide exchange factor ...by attachment, substitution, deletion, insertion and/or modification of one or more amino acids or groups of amino acids. This special technical feature is not shared by any of the other species.

> The special technical feature of (*l*) is an amino acid sequence which is derived from the amino acid sequence of a naturally occurring Ras protein ...by attachment, substitution, deletion, insertion and/or modification of one or more amino acids. This special technical feature is not shared by any of the other species.

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of the endpoint to be measured as indicative of Ras pathway activation in cells are as follows:

m. "Cell reproduction"

n. "activate transcription factors for genes which are not essential for cell reproduction" or expression of a reporter gene,

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 25, 37, 38, 45, 46, 50, 51, 53, 55, 58, 59

The following claim(s) are generic: 23, 36,44,49,52,56, for example.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (*m*) is cell reproduction. This special technical feature is not shared by any of the other species.

The special technical feature of (*n*) is transcription of genes which are not essential for cell reproduction. This special technical feature is not shared by any of the other species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D. whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

dcg